

Notice of Allowability

Application No.

09/719,554

Examiner

Stacy B Chen

Applicant(s)

ALLIEL ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to July 9, 2004.
2. ☒ The allowed claim(s) is/are 41-43, 46-51 and 57-60.
3. ☒ The drawings filed on 19 March 2003 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>July 9, 2004</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Vincent Shier on September 29, 2004.

The application has been amended as follows:

IN THE CLAIMS:

Claims 40 and 52-56 have been cancelled.

41. (Currently Amended) A diagnostic reagent for the differential detection of a human endogenous retroviral sequence, said diagnostic reagent comprising one or more isolated polynucleotides according to Claim 57.

46. (Currently Amended) A method for the differential detection of a human endogenous retroviral sequence, comprising:

(a) contacting a biological sample with at least one diagnostic reagent comprising according to Claim 41, and

(b) detecting a nucleotide sequence-diagnostic reagent interaction;

wherein the detection of a nucleotide sequence-diagnostic reagent interaction indicates the presence of the human endogenous retroviral sequence.

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47. (Currently Amended) A method for the differential detection of a human endogenous retroviral sequence, comprising:

- (a) preparing a biological tissue or fluid,
- (b) extracting a nucleic acid to be detected,
- (c) contacting the nucleic acid with at least one diagnostic reagent according to Claim 41,
- (d) detecting a nucleotide sequence-diagnostic reagent interaction, and
- (e) comparing the nucleotide sequences obtained from said detecting with a

polynucleotide selected from the group consisting of:

- i. one of SEQ ID NO: 1, 2, and 3,
- ii. the sequence complementary to one of SEQ ID NO: 1, 2, and 3, and
- iii. a sequence that is the reverse complement to one of SEQ ID NO: 1, 2, and 3;

wherein said comparing identifies an insertion, deletion or mutation between said sequences compared.

49. (Currently Amended) A method for the differential detection of a human endogenous retroviral sequence, comprising:

collecting messenger RNAs obtained from a control biological sample and from a sample collected from patient, and

analyzing qualitatively and/or quantitatively said mRNAs using a diagnostic reagent according to Claim 41 by a technique selected from the group consisting of *in situ* hybridization, by dot-blot, Northern blotting, RNase mapping and RT-PCR.

57. (Currently Amended) An isolated polynucleotide sequence selected from the group consisting of:

- a) the polynucleotide sequence of SEQ ID NO: 3;
- b) the complementary sequence to the sequence of a);
- c) the reverse complementary sequence to the sequence of a) or b);
- d) a fragment of a coding region of the sequence of a), wherein said fragment corresponds to a coding frame of at least 14 nucleotides; and
- e) the complementary sequence to the sequence of d).

58. (Currently Amended) The isolated polynucleotide according to Claim 57, wherein said fragment in d) consists of SEQ ID NO: 1 or SEQ ID NO: 2.

59. (Currently Amended) The isolated polynucleotide according to Claim 57, wherein said fragment in d) consists of a sequence encoding the C-terminal portion of enverin wherein said sequence begins at the codon at positions 8749 to 8751 of SEQ ID NO: 3 and contains at least 14 nucleotides.

60. (Currently Amended) The isolated polynucleotide according to Claim 57, wherein said fragment in d) consists of a sequence encoding the C-terminal portion of enverin wherein said sequence begins at the codon at positions 8839 to 8841 of SEQ ID NO: 3 and contains at least 14 nucleotides.

Examiner's Comment

2. Claims 46-51 have been rejoined, being drawn to methods of use of the allowable product in claims 57-60 and 41-43. The amendment to the method claims (claims 46, 47, 49, 57) were made to clarify claim language and for consistency with the product claims. The added clause at the end of claim 46 further correlates the method steps with the preamble of the claim. The added clause at the end of claim 47 further clarifies the step of "comparing" and the purpose of comparing. The amendment to claim 41 makes the claim dependent on the polynucleotide claim of claim 57. The amendment to claims 41 also removes non-elected subject matter. The amendment to claim 57 makes the claim the broadest independent claim, and also removes non-elected subject matter. The amendments to claims 58-60 were made in order to use language consistent with the other claims. For clarification, the acronym "SSCP" in claim 48 stands for "single strand conformation polymorphism" (specification page 49, line 23).

Conclusion

3. Claims 41-43, 46-51 and 57-60 as amended are allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

SBC

Stacy B. Chen
September 30, 2004

James C. Housel
10/1/04

JAMES HOUSEL
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